REMARKS

STATUS OF THE CLAIMS

With the entry of this amendment, the status of the claims will be as follows:

Claims **1, 7-9, 15, 31-33, 39, 43, 66, 69, 77** and **97** are unchanged from their originally filed form (original).

Claims **2, 16** and **70** were previously presented (previously presented).

Claims **14, 48** and **85** are currently amended herein.

Claims **98-106** are presented for the first time (new).

Claims **3-6, 10-13, 17-30, 34-38, 40-42, 44-47, 49-65, 67, 68, 71-76, 78-84** and **86-96** are cancelled.

This amendment to the claims is fully supported by the specification as originally filed. The claim amendments do not introduce new matter. These amendments are made without prejudice and are not to be construed as abandonment of previously claimed subject matter. The locations of support in the specification for the amendments to the claims is provided in the table below.

Claim Number	Location of Support in the Specification
14	Elements have been removed from the claim. No new elements are added by way of this amendment.
48	Elements have been removed from the claim. No new elements are added by way of this amendment.
85	Elements have been removed from the claim. No new elements are added by way of this amendment.
98	The elements recited in this claim were previously cited in claim **14**. These elements are now dependent from claim **1**.
99	See paragraphs 0132-0136.
100	See paragraphs 0138-0141.
101	The elements recited in this claim were previously cited in claim **48**. These elements are now dependent from claim **39**.
102	See paragraphs 0132-0136.
103	See paragraphs 0138-0141.
104	The elements recited in this claim were previously cited in claim **85**. These elements are now dependent from claim **69**.
105	See paragraphs 0132-0136.
106	See paragraphs 0138-0141.

Applicants respectfully request entry of the amendment prior to a first office action on the merits.

RESPONSE TO THE REQUEST FOR RESTRICTION

In the Office Action dated July 3, 2007, the Examiner requested restriction to one of the following groups of claims:

Group I: All pending claims except claim 8 (*i.e.*, claims 1, 2, 7, 9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85 and 97), as they relate to *increasing* carotenoid accumulation in a pineapple plant or plant cell.

Group II: All pending claims except claim 7 (*i.e.*, claims 1, 2, 8, 9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85 and 97), as they relate to *decreasing* carotenoid accumulation in a pineapple plant or plant cell.

In addition, when either of the groups above is selected, the Examiner has further required the selection of a single nucleic acid expression regulator. The Examiner states that this requirement is not an election of species requirement. The Examiner states that these choices are:

1) sense;
2) anti-sense;
3) transcription factor;
4) promoter/enhancer;
5) heterologous carotenoid biosynthetic polynucleotide; and
6) homologous carotenoid polynucleotide.

Choices for the carotenoid biosynthetic polypeptide expression regulator were previously included in dependent claims 14, 48 and 85. Applicants point out that claim 48 recited seven (not six) choices for the expression regulator. The Markush group elements of claims 14, 48 and 85 have been removed and are now itemized in new claims 98, 101 and 104.

The selection of a group for examination is made in view of the amended claims. Applicants hereby elect for prosecution the claims of Group I as they relate to *increasing* carotenoid accumulation. Applicants respectfully request the inclusion of new claims 98-106 in Group I as those claims relate to *increasing* carotenoid accumulation. Further, applicants elect with traverse a nucleic acid that encodes a carotenoid biosynthesis polypeptide that is *heterologous* to a pineapple host cell. This election reads on claims 1, 2, 7, 9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85 and 97-106.

TRAVERSAL

As an initial matter, Applicants do not traverse the restriction of the claims based on the "increasing carotenoid accumulation" or "decreasing carotenoid accumulation" criteria.

Applicants traversal is specifically with respect to the Examiner's requirement for the selection of a single nucleic acid expression regulator from the Markush groups of expression regulators found in previously presented claims 14, 48 and 85. These claims been amended, and these same Markush groups are now found in new claims 98, 101 and 104. The Examiner states that these various expression regulators are allegedly directed to six independent and distinct inventions, and create a serious burden on the Examiner if a restriction is not made.

Applicants disagree. The Markush groups cited by the Examiner are found in dependent claims. Traversal is made on the grounds that it is unclear how the elimination of the members of a Markush group in a dependent claim will limit the invention. The plurality of members in a Markush group in a dependent claim can not impact the alleged finding for a plurality of distinct inventions, when the independent claims (claims 1, 39 and 69) are clearly directed to a single invention. If the Examiner believes that a significant burden exists in examining all dependent claims, then an election of species may be appropriate in circumstances where the members of the Markush group are united by a generic claim. Such is the case in the present application, where the members of the Markush groups in question are united by the generic feature "carotenoid biosynthetic polypeptide expression regulator" as found in independent claims 1, 39 and 69.

The examiner's request to select one member of the Markush groups for examination as part of a restriction requirement is improper. It is unclear if the Examiner is requesting amendment to the claims to eliminate the unselected members of the Markush groups. If so, such a request is clearly improper.

Strangely, the Action asserts that further restriction of the claims is proper, because each nucleic acid expression regulator must be searched by a different query of the electronic database, citing MPEP § 808.02(c), allegedly resulting in undue burden. In fact, this section of the MPEP relates to the possibility that different inventions will require a different *search classification*, not that different *search terms* might (or might not) be appropriate for different

aspects of an invention. No different search *classifications* are alleged for any of the groupings because all claims are directed to methods for producing pineapple cells (and the pineapple cells themselves) having increased levels of carotenoid. It is rather apparent that the same search classification should be used in all searches, a fact that ordinarily would provide an appropriate reason why a restriction should *not* be made.

Furthermore, while it might be possible to design and separately execute a separate search for each possible expression regulator and its use in producing pineapple cells having increased levels of carotenoid, this is obviously not the most efficient search strategy in the present case. Instead of searching the expression regulators individually, the databases can instead be searched for correlations between "expression regulators" and "carotenoid accumulation" generically, which should identify relevant art for any particular expression regulator. Indeed, even if a separate query for each expression regulator is desired (it is plainly not "required" for a comprehensive search), there is still no reason why different expression regulators cannot be grouped into a single logical Boolean search query, along the lines of "carotenoid accumulation" and antisense" or "transcription factor" or "promoter/enhancer" or "homologous/heterologous biosynthetic polypeptide."

In any case, "separate query" is not a recognized standard for restriction practice. Indeed, it has long been settled that:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334 (In Re Weber et al. 198 USPQ 328 (CCPA 1978).

35 USC § 121 DOES NOT PROVIDE A BASIS FOR CLAIM AMENDMENTS

Applicants note that all case law addressing the issue of restricting a claim into parts away from itself, as the present office action requires for the subject claims, is perfectly clear that the Office **flatly lacks the authority to use 35 USC § 121 as a basis for forcing amendment of a claim**. The Courts have repeatedly stated that the divisional statute provides no basis at all for the separation of claim elements within a single claim, as the Office has here required (*i.e.*, restricting the case to one expression regulator from the claims). As the Courts have noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

It has, thus, long been held that the Office simply may not restrict a particular claim on the basis that it claims independent and distinct inventions. See, In *Re Weber, Soder and Boksay*, *supra*. The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, **even if the claim presents multiple independently patentable inventions**. *See, In Re Weber, Soder and Boksay, In Re Haas I* and *In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for "misjoinder" (rejection for inclusion of multiple independent inventions within a claim) despite previous attempts by the Patent Office to fashion such a rejection. For example, *In re Webber* (198 USPQ 328) sets forth the following (*see*, 331-332):

> It is apparent that §121 provides the commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner, acting under the authority of the commissioner to reject a particular claim on the same basis.

In re Haas (198 USPQ 335) interprets this as a *per se* holding, in the very next case by the court:

> In *In re Weber*... decided of even date, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed as a basis for rejection, that rejection is, on the authority of Weber, reversed.

As the Courts have repeatedly-- and pointedly-- indicated, the Office simply may not refuse to examine a claim, no matter how many inventions it embraces.

SPECIAL CONSIDERATIONS REGARDING UNITY OF INVENTION

Because the MPEP seems at first glance to consider restriction practice of Markush style claims with respect to Unity of Invention (MPEP 803.02), a great deal of confusion has, unfortunately, become commonplace in the Office as to appropriate restriction practice when considering questions of unity of invention for Markush style claims. It is instructive to consider how this section arose in the MPEP to understand what the law is and what it is not when performing this analysis.

After the *Weber* decision, noted above, a previous version of 803.02 that purported to fashion a rejection for "misjoinder" of a Markush-style claim was actually cancelled out of the MPEP. That is, for a time, the section corresponding to MPEP 803.02 simply stated: "the subject matter formerly under this subtitle has been cancelled in view of the decisions In Re Weber et al. 198 USPQ 328 (CCPA 1978) and In Re Haas 198 USPQ 334 (CCPA 1978)."

In 1980, the Courts again considered the issue of "misjoinder" in the seminal case of *In Re Harnisch* 206USPQ2d 1059, which considered whether there was a **non-statutory** basis for a rejection for lack of unity ***that was entirely distinct from restriction practice authorized by 35 USC 121***. The Court was plainly concerned that the two issues would be confused, noting that:

> It should be clear from what we have said that we adhere to our holdings in In re Weber, supra and In Re Haas (Haas II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be construed to have such an effect. The "unity of invention" concept is not to be confused with the "misjoinder" under 35 USC 121 rejection employed in In re Weber. In Weber, we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an improper Markush group."

The Court's concern that the Patent Office would confuse the issues of divisional practice under 35 USC § 121 and unity of invention practice has proven to be well founded. In reinstating MPEP § 803.02, the organizers of the MPEP addressed *Harnisch* (it is the Court decision that now underlies the section), but awkwardly left the original previously cancelled headings for the section in place, seeming to suggest that the issue is really one of restriction practice. As the Court plainly and expressly made clear (*see above*), it is not.

Indeed, as the *Harnisch* court made as clear as humanly possible, the issue when considering "improper Markush" is not an issue of restriction practice at all. Instead, the as the court bluntly stated above, the possibility that a Markush-style claim may lack of unity of invention, is a *"distinct ground"* of rejection. It has nothing at all to do with restriction practice. *Id.* As *Harnisch* makes entirely clear, ***improper Markush is not a basis for imposing a restriction requirement at all.***

Indeed, even the underlying Board of Appeals decision that was under consideration by the Federal Circuit in the *Harnisch* case had already **reversed** the improper Markush rejection by the Examiner, which had been based upon 35 USC § 121 (*Haas* and *Weber*, discussed above, plainly required this result), and fashioned a *different* improper Markush rejection based upon "unity of invention," an issue gleaned not from statute, but from consideration of judicial precedents (Harnisch at 304-305). The Court acknowledged the *possibility* of such a "unity of invention" style improper Markush rejection under various court precedent (but *not* under statute and, as specifically noted, ***not under 35 USC §121!***), but found that a rejection was proper *only* where the members of the Markush group were "truly independent *and* distinct." *Id.* at 306, *emphasis in the original.* The Court made quite plain that this was a high hurdle and that the Office had *not* shown a lack of unity in the relevant case, because the subject Markush members at issue were all dyes and could, accordingly, be classified together in a manner that was not "repugnant to scientific classification." *Id.* at 305.

Accordingly, even if "unity of invention" cannot be found amongst the members of a Markush, 35 USC § 121 *still* does not provide a basis for *restriction* as the Office has done in the present case. As the noted above, there is simply no such thing as a rejection for misjoinder and, accordingly, rather than restricting elements of a claim away from themselves, the only option open to the Office when attempting to make a rejection for lack of unity of invention is to attempt to make a rejection for improper Markush, a rejection that presents a high hurdle for the Office. As the Courts have definitively ruled, the Office flatly lacks the statutory authority to fashion such a rejection pursuant to *restriction* practice. There is no exception to this *per se* rule. The Courts have repeatedly noted the *per se* nature of this rule, as noted above. The Courts have never held otherwise.

In summary, it is clear that the present Office Action confuses the concepts of restriction practice and improper Markush and, in addition, does *not* establish the requisites for either. In the case underlying MPEP 803.02, *i.e.*, *In Re Harnisch,* the Court strongly reiterated that the divisional statute ***does not provide the basis for a rejection of the claims***, even in the context of a Markush-style claim. *In Re Harnisch* 206USPQ2d 300, see, *e.g.*, headnote 6 and page 305. As clearly articulated by the *Harnisch* Court, the *only* procedure available to the Office if unity of invention is lacking is to reject the claim for improper Markush on that basis—an event that takes place not under the auspices of divisional practice articulated by 35 USC § 121, or, indeed, as the *Harnisch* Court clearly articulated, *any* statutory section, but under judicially recognized precedent with respect to "unity of invention." The hurdle in making such a unity rejection is *high*, *i.e.*, that the members of the Markush group must be "truly independent *and* distinct" (emphasis in the original) or, as the Court stated another way "repugnant to scientific classification." This cannot be established in the present case. The members of the present Markush groups are all nucleic acids that can be delivered to a pineapple cell and can result in controlling the accumulation of carotenoid in the cell. No rejection under the standard articulated in Harnisch is remotely possible. Thus, there is no basis at all in the subject case for making an improper Markush rejection, any more than there is a basis for restriction of individual components of a claim away from themselves.

THE RESTRICTION REQUIREMENT PLACES A BURDEN ON THE APPLICANT

Although not expressly stated in the Office Action, compliance with the Action will require that each expression regulator in the Markush groups of claims 98, 101 and 104 be separated out of each claim and pursued in a separate divisional application. Even ignoring the profound cost implications in filing so many divisional patent applications, there is no way in which Applicants can recapture the scope of the claims as drafted.

Also, a significant feature of the invention is the ability to simultaneously utilize more than one type of expression regulator in a cell for the purpose of increasing the accumulation of a carotenoid in the cell. This is clearly conveyed by the "at least one" language in the independent claims as well as dependent claims 98, 101 and 104. Cancellation of members of the Markush group will deny the Applicant from capturing that embodiment of the invention.

CONCLUSION

Applicants have a constitutional and statutory right to have their invention examined and the Office as an administrative body is bound to recognize these rights. For the reasons noted above, the restriction requirement isolate only one member of the Markush groups for examination is improper and must be withdrawn.

In the event that the restriction is maintained in its current form, Applicants respectfully request an interview with the Examiner and the Examiner's SPE to discuss the subject restriction requirement prior to any action on the merits. Applicants encourage the Examiner to telephone the undersigned at (510) 337-7871.

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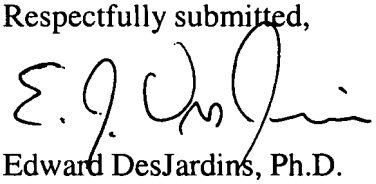
Respectfully submitted,



Edward DesJardins, Ph.D.
Reg. No: 51,162

Attachments:

1) A petition to extend the period of response for **two** months;
2) A transmittal sheet;
3) A fee transmittal sheet;
4) A receipt indication postcard.